LISTING OF THE CLAIMS

Please amend claims 1 and 13, and cancel claims 2-12, as indicated below.

Claim 1. (currently amended) A composition of a purified HMG-CoA reductase inhibitor having a purity of at least 99.7%, ~~wherein the HMG-CoA reductase inhibitor is selected from the group consisting of pravastatin and mevastatin~~ the composition consisting of pravastatin sodium salt and a total level of impurity of not more than 0.3%.

Claims 2-12. (cancelled)

Claim 13. (currently amended) A composition of pravastatin sodium salt ~~consisting of pravastatin sodium salt and~~ according to claim 1, wherein the total level of impurity includes a reduced level of at least one impurity selected from the group consisting of:

- (aR,bR,1S,2S,6S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-hydroxy-1-naphtaleneheptanioic acid monosodium salt,
- (aR,bR,1S,2S,6R,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-hydroxy-1-naphtaleneheptanioic acid monosodium salt,
- (aR,bR,1S,2S,6S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-((2S)-2-methyl-(3S)-3-hydroxy-1-oxobutoxy)-1-naphtaleneheptanioic acid monosodium salt,
- (aR,bR,1S,2S,6S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-((2S)-2-methyl-(3R)-3-hydroxy-1-oxobutoxy)-1-naphtaleneheptanioic acid monosodium salt,
- (aR,bR,1S,2S,6R)-1,2-dihydro-b,d,6-trihydroxy-2-methyl-1-naphtaleneheptanioic acid monosodium salt,

- (aR,bR,1S,2S,6S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-1-naphtaleneheptanioic acid monosodium salt,
- (aR,bR,1S,2S,6R,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-((2S)-2-methyl-1-oxobutoxy)-1-naphtaleneheptanioic acid monosodium salt,
- (aR,bR,1S,2S,6S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-((2S)-2-methyl-1-oxo-2-3-en-butoxy)-1-naphtaleneheptanioic acid monosodium salt,
- (aR,bR,1S,2S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,3-trihydroxy-2-methyl-8-((2S)-2-methyl-1-oxobutoxy)-1-naphtaleneheptanioic acid monosodium salt,
- (aR,bR,1S,2S,6S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-((2S)-2-methyl-1-oxopentoxy)-1-naphtaleneheptanioic acid monosodium salt,
- (aR,bR,1S,2S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d-dihydroxy-2-methyl-8-((2S)-2-methyl-3-hydroxy-1-oxobutoxy)-1-naphtaleneheptanioic acid monosodium salt, and
- (aR,bR,1S,2S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d-dihydroxy-2-methyl-8-((2S)-2-methyl-4-hydroxy-1-oxobutoxy)-1-naphtalennheptanioic acid monosodium salt.

Claim 14. (original) A composition of pravastatin sodium salt according to claim 13, wherein an individual impurity selected from the group consisting of:

- (aR,bR,1S,2S,6S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-hydroxy-1-naphtaleneheptanioic acid monosodium salt,
- (aR,bR,1S,2S,6S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-((2S)-2-methyl-(3R)-3-hydroxy-1-oxobutoxy)-1-naphtaleneheptanioic acid monosodium salt,
- (aR,bR,1S,2S,6S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-((2S)-2-methyl-1-oxopentoxy)-1-naphtaleneheptanioic acid monosodium salt,

- (aR,bR,1S,2S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d-dihydroxy-2-methyl-8-((2S)-2-methyl-3-hydroxy-1-oxobutoxy)-1-naphtaleneheptanioic acid monosodium salt, and
- (aR,bR,1S,2S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d-dihydroxy-2-methyl-8-((2S)-2-methyl-4-hydroxy-1-oxobutoxy)-1-naphtalennheptanioic acid monosodium salt,

is present in an amount of below the limit of determination.

Claim 15. (original) A composition of pravastatin sodium salt according to claim 13, wherein an individual impurity selected from the group consisting of:

- (aR,bR,1S,2S,6R,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-hydroxy-1-naphtaleneheptanioic acid monosodium salt,
- (aR,bR,1S,2S,6S,8S,8aR)-1,2,6,7,8,8a-Hexahydro-b,d,6-trihydroxy-2-methyl-8-((2S)-2-methyl-(3S)-3-hydroxy-1-oxobutoxy)-1-naphtaleneheptanioic acid monosodium salt, and
- (aR,bR,1S,2S,6R)-1,2-dihydro-b,d,6-trihydroxy-2-methyl-1-naphtaleneheptanioic acid monosodium salt,

is present in an amount of below 0.01 % area.

Claim 16. (original) A composition of pravastatin sodium salt according to claim 13, wherein an individual impurity selected from the group consisting of:

- (aR,bR,1S,2S,6S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-1-naphtaleneheptanioic acid monosodium salt,
- (aR,bR,1S,2S,6R,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-((2S)-2-methyl-1-oxobutoxy)-1-naphtaleneheptanioic acid monosodium salt, and

- (aR,bR,1S,2S,6S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-((2S)-2-methyl-1-oxo-2-3-en-butoxy)-1-naphtaleneheptanioic acid monosodium salt,

is present in an amount of below 0.1 % area.

Claim 17. (original) A composition of pravastatin sodium salt according to claim 13, wherein the impurity (aR,bR,1S,2S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,3-trihydroxy-2-methyl-8-((2S)-2-methyl-1-oxobutoxy)-1-naphtaleneheptanioic acid monosodium salt is present in an amount of below 0.05 % area.

ELECTION OF THE CLAIMS

In response to the Office Action of May 16, 2005 requiring restriction of the claims to a single invention, Applicants were asked to elect either group I, claims 1-5, drawn to a HMG-CoA reductase inhibitor; Group II, claims 6-12, drawn to a process for purification of a HMG-CoA reductase inhibitor; or Group III, claims 13-17, drawn to a composition of pravastatin salt. Applicants called Examiner Shameem on June 25, 2004 and July 1, 2004 in response to Examiner Shameem's telephone call of June 15, 2004 to discuss how to elect both Groups I and III, but no consensus for how best to achieve that goal was reached, and no election was made. In this response, Applicants submit amended claims 1 and 13, such that both are now drawn to a composition of pravastatin salt. Applicants thus respectfully request that claims 1 and 13-17 (excepting cancelled claims 2-12) be examined on the merits.

In addition, Applicants traverse the original requirement for electing a single compound of impurity for claim 13, because amended claim 1 is now drawn to composition consisting of a single compound - pravastatin sodium salt - with a reduced level of total impurity not more than 0.3%. In addition, amended claim 13, reciting that the total impurity described in claim 1 includes at least one impurity selected from the listed group, is now dependent on claim 1. None of the amended claims is drawn to the impurities themselves; each claim is drawn to a composition of pravastatin sodium salt. Therefore Applicants respectfully submit that it is not proper to require election of a single impurity, particularly when the claim is directed to a composition of pravastatin sodime salt, not to the impurity.

Support for the Claim Amendments

Support for amended claim 1 is found in the application on p. 9, middle two paragraphs; p. 10 through p. 16; pp. 19-22, examples 1-4 and Table 1; on pp. 26-27 in Example 15, and in original claims 13-17.